

Remarks

I. Interview Summary

Applicant wishes to thank the Examiner for considering the issues raised in the July 6, 2009 Office Action during the interview on October 21, 2009. During the interview, the Examiner and Applicant's attorney discussed the cited prior art and claim amendments that would distinguish the prior art. The claim amendments discussed in the interview are reflected above. The remainder of the substance of the interview is further reflected below. Applicant believes the application is now in a condition for allowance and appreciates the Examiner's due consideration of the amendments above and the following comments.

II. Introduction

Claims 40-47, 49, 50, and 73-90 are pending in the application, including independent claims 40, 78, 84, and 90. In the Office Action dated July 6, 2009, claims 40-47, 49, 50, and 73-90 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 6,080,191 ("Summers") in view of U.S. Pat. No. 6,010,529 ("Herweck"), U.S. Pat. No. 5,843,166 ("Lentz II"), and U.S. Pat. No. 5,951,599 ("McCrory").

Applicant has carefully considered the Examiner's comments. In order to expedite prosecution of Applicant's claims, claims 40, 73-75, 79, 84, 85, and 90 have been amended, and claims 49, 50, 80, 81, 86, and 87 have been cancelled. Applicant respectfully requests reconsideration and withdrawal of the rejections in light of the amendments to the claims and the following remarks.

III. The Proposed Combination Does Not Render Independent Claims 40, 78, 84, and 90 Unpatentable.

Independent claims 40, 78, 84, and 90 were rejected as being unpatentable over Summers in view of Herweck, Lentz II, and McCrory. As amended, each of claims 40, 78, 84, and 90 recites in part:

a graft material disposed on a portion of the support frame and spanning **a portion of the length**, the graft material extending only a partial distance along a circumference of the support frame, said partial distance being at least about $\frac{1}{4}$, of the circumference;

wherein said graft material is secured to said support frame by folding one end of said graft material around **a first intermediate frame thread displaced from a first end of the support frame** and along an inner surface of the support frame thereby having an area of double thickness of two layers of said same graft material and affixing said two layers to each other without connecting said graft material to said one of said frame threads and folding an opposite end of said graft material around **a second intermediate frame thread displaced from a second end of the support frame** and along the inner surface of the support frame thereby having an area of double thickness of two layers of said graft material and affixing said two layers to each other without connecting said graft material to said another of said frame threads, said two layers remaining affixed to each other even after said intraluminal support device is deployed in said body vessel, **said graft material thereby extending over only a longitudinally intermediate portion of said support frame.**

An exemplary embodiment of an intraluminal device covered by the amended independent claims is shown in, for example, Figure 4 of the present application. As Figure 4 illustrates, the graft material extends only a fraction of the length of the support frame and is attached at its ends to intermediate frame threads, such that the graft extends only over a longitudinally intermediate portion of the support frame.

Turning to the rejection, the combination of Summers, Herweck, Lentz II, and McCrory as contemplated by the Examiner fails to disclose at least the above recited elements of the independent claims.

In the present Office Action, the Examiner has acknowledged that Summers fails to disclose “the specific means of attaching the graft to the stent frame [recited in the claims].” Office Action dated March 4, 2009, p.2. Indeed, the only mention of grafts in Summers is in reference to “a **tube-shaped member** having an inside diameter only slightly larger than the circumference of the deployed stent.” Col. 11, lines 28-31. As described below in detail, such tubular grafts cannot be modified to form the structure required by the amended independent claims.

Specifically, Summers fails to disclose securing a graft material to a support frame by folding one end of the graft around **a first intermediate frame thread displaced from a first end of the support frame** and along an inner surface of the support frame thereby having an area of double thickness of two layers of said graft material and affixing said two layers to each other without connecting said graft material to said one of said frame threads, as recited in the independent claims. Summers also fails to disclose folding an opposite end of the graft material around **a second intermediate frame thread displaced from a second end of the support frame** and along the inner surface of the support frame thereby having an area of double thickness of two layers of the graft material and affixing the two layers to each other without connecting the graft material to the another of the frame threads, the graft material thereby **extending over only a longitudinally intermediate portion of the support frame**, as recited in amended independent claims 40, 78, 84, and 90.

In an effort to cure Summers’ deficiencies, the Examiner has cited Herweck. However, Herweck also fails to disclose the above-recited elements of amended claims 40, 78, 84, and 90.

Herweck is directed to a radially expandable support body **enveloped within a cocoon**. Abstract. As shown in the embodiments of Figures 2-4C, **a tube of PTFE is passed through the interior of the stent and is cuffed**, e.g. folded back upon itself, over the stent, in a manner similar to the folding of a sock, so that the folded-back end of the tube becomes an outer layer smoothly

extending around the end and covering the outside of the stent. Col. 2, lines 40-48; Col. 4, lines 30-45. The assembly is then heated, causing the outer layer to shrink and coalesce with the inner layer so that the stent is enclosed within a folded envelope having a continuous and seamless end portion. Col. 2, lines 48-51; Col. 4, lines 45-49. Radial pressure is also applied during the heating so that the layers conform tightly to the support body and fill all interstitial spaces thereof. Col. 2, lines 51-53; Col. 4, lines 49-53. In other constructions, support members lie within pockets extending in the direction of expansile deformation. Col. 2, lines 53-55; Col. 5, lines 17-33.

In contrast, the independent claims require a graft material that is secured to the support frame by folding one end of the graft material around **a first intermediate frame thread displaced from a first end of the support frame** and along an inner surface of the support frame thereby having an area of double thickness of two layers of the same graft material and affixing the two layers to each other without connecting the graft material to the one of the frame threads and folding an opposite end of the graft material around **a second intermediate frame thread displaced from a second end of the support frame**. As set forth above, Herweck discloses **a tube of PTFE that is passed through the interior of the stent and is cuffed** so that the folded-back end of the tube becomes an outer layer smoothly extending around the end and covering the outside of the stent. As known in the art and shown in, for example, Figures 1A-4C of Herweck, any stent structure must have longitudinally extending members of one form or another (e.g. the helically extending stent of Herweck) to span the distance from one end of the stent to the other. Because these longitudinal members must be present, it is impossible for a **tubular graft** that extends around the entire circumference like Herweck to be attached to a stent around an **intermediate frame thread that is displaced from an end of the stent** because the longitudinally extending members, e.g. the intermediate portions of the helically extending zigzag structure of Herweck would interfere with and prevent the tubular graft from being folded over to form a cuff at any point other

than at the very ends of the stent. That is, a folded over “cuff,” as disclosed in Herweck is impossible to achieve in a longitudinally intermediate portion of the stent because the longitudinal members of the stent prevent such folds. Indeed, the only way a tubular graft can be folded over on itself and attached to a graft is by extending the graft beyond the end of the stent structure, as discussed in Herweck. A cuff cannot be formed using the tubular graft disclosed in Herweck at a longitudinally intermediate portion as recited in Applicant’s amended claims.

Thus, it is impossible to modify the tubular, full graft of Herweck for use in a partial graft that is attached to a support frame by folding the graft material around **first or second intermediate frame threads displaced from first or second ends of the support frame** and along an inner surface of the support frame thereby having an area of double thickness of two layers of the same graft material and affixing the two layers to each other without connecting the graft material to the one of the frame threads, **the graft material thereby extending over only a longitudinally intermediate portion of the support frame**. Accordingly, Herweck does not and cannot disclose at least the above recited elements of the independent claims.

Like Herweck and Summers, Lentz II also fails to disclose the above recited elements of the independent claims. In the present Office Action, the Examiner has relied on Lentz II as disclosing the attachment of inner and outer layers of graft material to one another and not the stent. Office Action dated July 6, 2009, p.3. Significantly, Lentz II only discloses securing **first and second tubes** to each other by fusion or lamination. Lentz II does not disclose securing a graft to a support frame by folding one end of the graft material around **a first intermediate frame thread displaced from a first end of the support frame** and along an inner surface of the support frame thereby having an area of double thickness of two layers of the same graft material and affixing the two layers to each other without connecting the graft material to the one of the frame threads and folding an opposite end of the graft material around **a second intermediate frame thread displaced from a second end of the support frame** and along

the inner surface of the support frame thereby having an area of double thickness of two layers of the graft material and affixing the two layers to each other without connecting the graft material to the another of the frame threads, the two layers remaining affixed to each other even after the intraluminal support device is deployed in the body vessel, **the graft material thereby extending over only a longitudinally intermediate portion of the support frame**, as recited in the independent claims. Thus, like Herweck and Summers, it is impossible to modify the tubular grafts of Lentz II to form the structure of the longitudinally intermediate partial graft recited in the independent claims.

Moreover, as detailed in Applicant's response to the previous Office Actions, McCrory also fails to teach or suggest at least the above recited elements of the independent claims.

For at least these reasons, the combination of Summers, Herweck, Lentz II, and McCrory as contemplated by the Examiner does not render independent claims 40, 78, 84, and 90, or any claim that depends therefrom, unpatentable, and the Examiner may withdraw the rejection.

IV. Conclusion

Applicant submits that the claims, as amended, patentably distinguish over the art of record. Applicant requests expedited consideration and allowance of this application. If for any reason the Examiner is unable to allow the Application but believes that an interview would be helpful to resolve any issues, the Examiner is respectfully requested to call the undersigned at (312) 840-3262.

Respectfully submitted,

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